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Office of Regulatory Policy  
HFD-7  
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Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 4,948,805 (the '805 patent) was filed on March 21, 2007, under 35 U.S.C. § 156 based on the regulatory review period for FLECTOR® PATCH (diclofenac epolamine topical patch). It is noted that Applicant also has applied for patent term extension for U.S. Patent No. 5,607,690 based on the same regulatory review period for FLECTOR® PATCH (diclofenac epolamine topical patch).

The assistance of your Office is requested in confirming that (i) the application for patent term extension was filed within the sixty-day period after the product was approved as required by 35 U.S.C. § 156(d)(1); and (ii) the product identified in the application, FLECTOR® PATCH (diclofenac epolamine topical patch), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use as required by 35 U.S.C. § 156(a)(5)(A). Our views on each issue are presented below. Since a determination has not yet been made whether the '805 patent claims FLECTOR® PATCH (diclofenac epolamine topical patch), as required by 35 U.S.C. § 156 (a), this communication is **NOT** intended to serve as notice under 35 U.S.C. § 156(d)(2)(A).

As to the first question, Applicant states in the PTE Application that the FDA approved the New Drug Application for FLECTOR® PATCH (diclofenac epolamine topical patch) on January 31, 2007. Applicant filed its PTE Application with the USPTO on March 21, 2007. Thus, Applicant's PTE Application is well within the sixty day application window set forth in 35 U.S.C. § 156(d)(1) and the USPTO in turn concludes that it was timely filed, thereby meeting the requirement of 35 U.S.C. § 156(d)(1).

As to the second question, our initial review of Applicant's PTE Application indicates that the '805 patent would **NOT** be eligible for extension of the patent term under 35 U.S.C. § 156, even though Applicant's PTE Application was timely filed, because FLECTOR® PATCH (diclofenac epolamine topical patch) does not constitute the first permitted commercial marketing or use of the "product" under the provision of law under which the regulatory review period occurred, here, 21 U.S.C. § 355 (section 505 of the Federal Food, Drug and Cosmetic Act). Our initial review shows that the FDA previously approved as human drugs under 21 U.S.C. § 355 both CATAFLAM® (diclofenac potassium) and VOLTAREN® (diclofenac sodium), the potassium and sodium salt forms of diclofenac, respectively. Thus, at issue in this case is whether the FDA's approval of FLECTOR® PATCH (diclofenac epolamine topical patch) authorized the first permitted commercial marketing or use of the product in accordance with 35 U.S.C. § 156.

Please note that the original expiration date of U.S. Patent No. 4,948,805, is November 9, 2007, as indicated in the application for patent term extension. The Federal Circuit in Somerset Pharma., Inc. v. Dudas, 207 U.S. App. LEXIS 18231 (Fed. Cir. 2007) held that the USPTO has no statutory authority to grant an interim extension [under 35 U.S.C. § 156(e)(2)] of a patent term beyond the term provided for by section 154 when the patent for which a term extension is sought "would expire before a certificate of extension is . . . denied." See Somerset, at 207 U.S. App. LEXIS at \*4 (quoting 35 U.S.C. 156(e)(2)) (this opinion reissued as precedential as of October 4, 2007). This means that should the USPTO deny Applicant's request for patent term extension [filed under 35 U.S.C. § 156(d)(1)], the USPTO has no authority to grant an interim extension under 35 U.S.C. 156(e)(2).

The following is the USPTO's detailed analysis of the relevant provisions of section 156 and judicial precedent on what it means for an approved product to represent the "first permitted commercial marketing or use of the product."

**I. The Plain Language of 35 U.S.C. § 156(f) Shows That FLECTOR® PATCH (diclofenac epolamine topical patch) Is Not the First Permitted Commercial Marketing or Use of the "Product" As Required by 35 U.S.C. § 156(a)(5)(A)**

In accordance with 35 U.S.C. § 156(e)(1), the USPTO has reviewed Applicant's PTE Application and has initially determined, based on the previous approval of CATAFLAM® (diclofenac potassium) and VOLTAREN® (diclofenac sodium), that the '805 patent, which allegedly protects FLECTOR® PATCH (diclofenac epolamine topical patch), is not eligible for a term extension. Section 156(a) of Title 35 sets forth several requirements that must be met before the Director can extend the term of a patent. See 35 U.S.C. §§ 156 (a)(1)-(a)(5), (d)(1), & (e)(1). Section 156(a)(5)(A) requires that

the permission for the commercial marketing or use of the product . . . [be] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

35 U.S.C. §156(a)(5)(A) (emphasis added). The term "product" as used in section 156(a)(5)(A) is defined in section 156(f)(1) as a "drug product," and the term "drug product" is defined in section 156(f)(2) as the "active ingredient of [a] new drug, antibiotic drug, or human biological product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." 35 U.S.C. § 156(f) (emphasis added). Hence, by the explicit terms of section 156(f)(2), "product" means "active ingredient," and "any salt or ester of the active ingredient."

By distinguishing "active ingredient" from salts and esters of the active ingredient, the statutory language of §156 makes clear that the active ingredient cannot be a salt or an ester. Put differently, the term "product" as used in §156 includes: (i) a non-salified and non-esterified form of a molecule (i.e., the "active ingredient"); (ii) a salt of the molecule (i.e., the "salt . . . of the active ingredient"); and (iii) an ester of the molecule (i.e., the " . . . ester of the active ingredient").

Because a “product” includes all three forms, a non-salified, non-esterified form of a molecule is statutorily the same “product” as a salt or ester of that molecule for purposes of the patent term extension provisions in § 156.

Prior to the approval of FLECTOR® PATCH (diclofenac epolamine topical patch), the FDA approved CATAFLAM® (diclofenac potassium) and VOLTAREN® (diclofenac sodium). It is clear that diclofenac is present in both CATAFLAM® and VOLTAREN® as the underlying molecule, formulated either as a potassium or sodium salt, respectively. It is also clear that diclofenac is present in FLECTOR® PATCH as the underlying molecule, formulated as an epolamine salt. Consequently, the approved “product,” as that term is defined in § 156, is the same in CATAFLAM®, VOLTAREN®, and FLECTOR® PATCH, *i.e.*, diclofenac and any salt or ester of diclofenac. As such, the later approved FLECTOR® PATCH (diclofenac epolamine topical patch) does not represent the first permitted commercial marketing or use of the “product” under the provision of law under which such regulatory review occurred. The USPTO therefore concludes that Applicant’s PTE Application does not satisfy the requirements of section 156(a)(5)(A) and the ’805 patent is not eligible for a patent term extension.

## **II. Judicial Precedent Confirms That FLECTOR® PATCH (diclofenac epolamine topical patch) Is Not the First Permitted Commercial Marketing or Use of the “Product” As Required by 35 U.S.C. § 156(a)(5)(A)**

Judicial precedent confirms that the USPTO’s application of the definition of “product,” as that term is used in section 156(a)(5)(A), is correct. In Fisons v. Quigg, 1988 WL 150851 (D.D.C. 1988) (“Fisons I”), the district court addressed the meaning of the term “product.” The district court considered both the plain language of section 156(a)(5)(A) and its legislative history. With respect to the latter, the district court observed:

Upon examination, the specific purpose of Section 156(a)(5)(A) appears to have been relatively narrow—to restore lost patent life only for “pioneer” drugs. A report by the Congressional Office of Technology Assessment (“OTA”) to the 97th Congress provided the factual foundation for the restriction of patent restoration benefits to new chemical entities. The OTA report stated: “Although important pharmaceutical innovations may result from new therapeutic applications of existing chemicals . . . many of the pharmaceutical breakthroughs that have occurred have resulted from NCE (new chemical entity) research and the development of NCEs generally has required more time and money than other types of innovation and has involved greater risks.” The House Committee on Energy and Commerce explained that the bill “requires extensions to be based on the first approval of the product because the only evidence available to Congress showing that patent time has been lost is data on so-called class I, new chemical entity drugs.”

Fisons I, 1988 WL 150851 at \*7. After making these observations, the district court found that “Congress’s intent was to restore patent life only to new chemical entities.” The district court thus construed section 156(a)(5)(A) in a straightforward way:

In the definitional provision of Section 156, the term “product” is defined as a “human drug product.” 35 U.S.C. § 156(f)(1)(A). This term is further defined in the next subparagraph as “the active ingredient of a new drug, antibiotic drug, or human biological product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.” 35 U.S.C. § 156(f)(2) (emphasis added in original). Substituting this definition directly back into Section 156(a)(5)(A) yields the statement that a patent is ineligible for extension if it is not the first permitted commercial marketing or use of the active ingredient contained in that approved patented product.

Id. at \*5.

The Federal Circuit affirmed the district court’s interpretation. Fisons v. Quigg, 876 F.2d 99 (Fed. Cir. 1989) (“Fisons II”). The Federal Circuit stated: “In sum, we hold that the district court correctly applied the definition given in 35 U.S.C. § 156(f) to the term ‘product’ used in section 156(a)(5)(A). We are convinced that such an interpretation comports with the intent of Congress as expressed in the statute.” Fisons II, 876 F.2d at 102.

The Federal Circuit later interpreted the term “active ingredient” in Pfizer, Inc. v. Dr. Reddy’s Labs., Ltd., 359 F.3d 1361 (Fed. Cir. 2004). There, the Federal Circuit accepted the FDA’s definition of the term “active ingredient” as meaning “active moiety.” Id. at 1366 (citing Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,358 (F.D.A. Oct. 3, 1994)). It likewise accepted that “active moiety” means “the molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . responsible for the physiological or pharmacological action of the drug substance” based upon the FDA’s regulations. Id. (quoting 21 C.F.R. § 314.108(a)) (omission in original). Hence, the Federal Circuit has construed the term “active ingredient” as used in section 156(f)(2) to mean the underlying molecule, *i.e.*, the molecule or ion responsible for the physiological or pharmacological action of the drug, excluding those appended portions of the molecule that cause the drug to be an ester or salt.

Substituting this definition for the word “active ingredient” as it appears in section 156, the term “drug product” in section 156(f)(2) must mean the underlying molecule as well as any salt or ester of the underlying molecule since it is defined as “active ingredient . . . including any salt or ester of the active ingredient.” Further, because “product” is defined as “drug product” in section 156(f)(1)(A), “product” likewise must mean the underlying molecule as well as to any salt or ester of the underlying molecule. That definition conforms with the plain language of section 156(f). What is more, the Federal Circuit confirmed in Pfizer that only the first approval for any given “active ingredient” can trigger a patent term extension under 35 U.S.C. § 156, regardless whether that first approval was for an underlying molecule, a salt of the underlying molecule, or an ester of the underlying molecule. Pfizer, 359 F.3d at 1366 (“The statute [referring to 35 U.S.C. § 156] foresaw variation in the salt or ester of an active ingredient, and guarded against the very loophole now urged. . . . [T]he text of the statute shows that it was not intended to be defeated by simply changing the salt.”).

Here, before approving FLECTOR® PATCH (diclofenac epolamine topical patch) in 2007, the FDA approved CATAFLAM® (diclofenac potassium) and VOLTAREN® (diclofenac sodium) in 1993 and 1988, respectively. As explained above, diclofenac is the underlying molecule in CATAFLAM® and VOLTAREN® as well as FLECTOR® PATCH. Diclofenac is simply formulated differently in these three different drugs, as a potassium salt in CATAFLAM®, as a sodium salt in VOLTAREN®, and as an epolamine salt in FLECTOR® PATCH. However, these salt formulation differences do not matter for purpose of section 156. The statutory definition of “product” includes the underlying molecule as well as any salt or ester of the underlying molecule. Accordingly, FLECTOR® PATCH (diclofenac epolamine topical patch) is not the first permitted commercial marketing or use of the “product” as required by 35 U.S.C. § 156(a)(5)(A) because of the earlier approvals of CATAFLAM® (diclofenac potassium) and VOLTAREN® (diclofenac sodium).

Finally, the FDA has issued a regulation defining the term “active ingredient” of a pharmaceutical “product” for purposes of patent term extension under 35 U.S.C. § 156. Specifically, 21 C.F.R. § 60.1(a) states that “[t]his part [referring to Part 60] sets forth procedures and requirements for the [FDA]’s review of applications for the extension of the term of certain patents under 35 U.S.C. § 156.” That provision further states that “[FDA] actions in this area include [*inter alia*] [a]ssisting the [USPTO] in determining eligibility for patent term restoration.” 21 C.F.R. § 60.1(a)(1). Section 60.3 then provides a series of definitions to be used in Part 60 in addition to the definitions already contained in 35 U.S.C. § 156. 37 C.F.R. § 60(b)(2) defines “active ingredient” for purposes of a patent extension to mean a drug’s active moiety, *i.e.*, its therapeutically active component. It states:

Active ingredient means any component that is intended to furnish pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or function of the body of man or of animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

21 C.F.R. § 60.3 (b)(2). Applying the FDA’s regulations in this case, diclofenac is for certain the “active ingredient” of not just CATAFLAM® and VOLTAREN® but also of FLECTOR®PATCH; it is simply formulated as three different salts.

The USPTO recognizes that Glaxo Operations UK, Ltd v. Quigg, 894 F.2d (Fed. Cir. 1990), also concerns section 156(f). However, the USPTO observes that Glaxo is factually distinguishable because the Federal Circuit did not address the definition of “active ingredient” in that case. Rather, the Federal Circuit focused on the USPTO’s argument that the term “product” did not have the literal meaning set forth in section 156(f)(2), but instead meant “any ‘new chemical entity,’ *i.e.*, ‘new active moiety.’” Rejecting that argument, the Federal Circuit explained that Congress provided a definition of the term “product” in section 156(f)(2) and that Congress “selected terms with narrow meanings that it chose from among many alternatives.” Glaxo, 894

F.2d at 399 (footnoting as examples of other possible words “new molecular entity,” “active moiety,” and “new chemical entity”). The Federal Circuit did not discuss the definition of the term “active ingredient” because, unlike here, the determination of the active ingredient was not in dispute in Glaxo.

The most that can be said about Glaxo is that the Federal Circuit acknowledged that the term “product” was not expressly defined by Congress to mean “active moiety,” since those words do not appear in section 156(f)(2). However, Glaxo does not hold that the term “active ingredient” as used in section 156(f)(2) does not mean “active moiety.” In fact, the Federal Circuit later accorded the term “active ingredient” with that precise definition in Pfizer. See Pfizer, 359 F.3d at 1366. Accordingly, the USPTO’s determination that the ’805 patent is ineligible for extension pursuant to section 156 is supported by, and consistent with, Glaxo.

Furthermore, as mentioned above, Pfizer is applicable here and factually similar because it addresses not only the exact statutory provision in dispute—section 156—but also the exact subparagraph in dispute—section 156(f)(2)—and the exact term in dispute—“product.” It is a well-established canon of statutory construction, in pari materia, that a legislative body generally uses a particular word with a consistent meaning in a given context. See Erlenbaugh v. United States, 409 U.S. 239, 244 (1972). As the Supreme Court has explained, “identical words used in different parts of the same act are intended to have the same meaning.” Sorenson v. Sec’y of the Treasury of the United States, 475 U.S. 851, 860 (1986) (quoting Atl. Cleaners & Dryers, Inc. v. United States, 286 U.S. 427, 433 (1932)).

Moreover, section 156(f) makes clear that the same definition of “product” is to be applied throughout section 156. Section 156(f) explicitly states that its provisions are “for purposes of this section.” Thus, the term “product” as used throughout 35 U.S.C. § 156—for eligibility under section 156(a) and for enforcement under section 156(b)—has but one meaning. And, as explained above, it means the “active ingredient” of a new drug, “including any salt or ester of the active ingredient” based on the plain language of 35 U.S.C. § 156(f)(2).

Here, the facts are similar to Pfizer. The earlier approved drugs, CATAFLAM® (diclofenac potassium) and VOLTAREN® (diclofenac sodium), are salts of diclofenac, the “product” for which the extension is now sought, i.e., FLECTOR® PATCH, an epolamine salt of diclofenac. That is, diclofenac potassium and sodium are the salts of diclofenac, and diclofenac is the “active ingredient” in the drug FLECTOR® PATCH (diclofenac epolamine topical patch). Diclofenac is simply formulated as a epolamine salt in FLECTOR® PATCH (diclofenac epolamine topical patch).

In sum, based on the plain language of section 156(f)(2) and judicial precedent, the USPTO concludes that the FDA’s approval of FLECTOR® PATCH (diclofenac epolamine topical patch) in 2007 does not constitute the first permitted commercial marketing or use of the “product” under the provision of law under which such regulatory review period occurred as required by 35 U.S.C. § 156(a)(5)(A). Therefore, the USPTO concludes that the ’805 patent is NOT be eligible for a patent term extension.

The USPTO looks forward to the FDA's requested assistance as to (i) confirming that Applicant's PTE Application was timely filed; and (ii) whether FLECTOR® PATCH (diclofenac epolamine topical patch) represents the first commercial marketing or use of the product under 21 U.S.C. § 355 (section 505 of the FFDCA). The USPTO anticipates receiving input as soon as possible given that the '805 patent will expire, according the PTE Application, by operation of law on November 9, 2007.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).



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